

providers beyond that experienced by dealerships.

(17) Manufacturers shall be responsible for ensuring that persons specified in paragraph (g)(1) of this section shall have access to reprogramming services at a reasonable cost and in a timely manner.

(18) Manufacturers shall provide persons specified in paragraph (g)(1) of this section with an efficient and cost-effective method for identifying whether the calibrations on vehicles are the latest to be issued.

(19) Manufacturers shall either make available to aftermarket tool and equipment companies no later than the date of model introduction any and all information, except calibrations and recalibrations, needed to develop and manufacture generic tools that can be used by persons specified in paragraph (g)(1) of this section to diagnose, service and repair emission-related parts, components and systems or manufacturers may sell their own diagnostic tools and equipment to persons specified in paragraph (g)(1) of this section if the price of such tools is reasonable.

(20) A manufacturer is subject to a penalty of up to \$25,000 per day per violation for failure to make available the information required by this section.

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#### 40 CFR Part 180

[PP 9F3818/R2153; FRL-4970-3]

RIN 2070-AB78

#### Tebuconazole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule establishes tolerances for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) for seed treatment in or on the raw agricultural commodities barley grain, forage, hay, and straw at 0.05, 0.10, 0.10, 0.10 parts per million (ppm), respectively; oat grain, forage, hay, and straw at 0.05, 0.10, 0.10, and 0.10 ppm, respectively; and wheat grain, forage, hay, and straw at 0.05, 0.10, 0.10, 0.10 ppm, respectively. Miles, Inc. (formerly Mobay Corp., Agricultural Chemicals Division, now Bayer Corp.) submitted a petition pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) for the regulation to establish a maximum

permissible level for residues of the fungicide.

**EFFECTIVE DATE:** This regulation becomes effective August 9, 1995.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 9F3818/R2153], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P. O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of any objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document number [PP 9F3818/R2153]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document. **FOR FURTHER INFORMATION CONTACT:** By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6226; e-mail: welch.connie@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the **Federal Register** of June 15, 1995 (60 FR 31465), which announced that Miles,

Inc., Agricultural Division (formerly Mobay Corp., Agricultural Chemicals Division, now Bayer Corp.), P.O. Box 4913, Kansas City, MO 64120-0013, had submitted pesticide petition (PP) 9F3818 to EPA requesting that the Administrator, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), establish a tolerance for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) for seed treatment in or on the raw agricultural commodities barley grain, forage, hay, and straw at 0.05, 0.10, 0.10, 0.10 ppm, respectively; oat grain, forage, hay, and straw at 0.05, 0.10, 0.10, and 0.10 ppm, respectively; and wheat grain, forage, hay, and straw at 0.05, 0.10, 0.10, and 0.10 ppm, respectively.

There were no comments received in response to the notice of filing.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. A 90-day rat feeding study with a no-observed-effect level (NOEL) of 34.8 milligrams per kilogram of body weight per day (mg/kg bw/day) (400 ppm) and a lowest-effect-level (LEL) of 171.7 mg/kg bw/day (1,600 ppm) in males, based on decreased body weight gains and histological changes in the adrenals. For females, the NOEL was 10.8 mg/kg bw/day (100 ppm), and the LEL was 46.5 mg/kg bw/day (400 ppm) based on decreased body weights, decreased body weight gains, and histological changes in the adrenals.

2. A 90-day dog feeding study with a NOEL of 200 ppm (73.7 mg/kg bw/day in males and 73.4 mg/kg bw/day in females) and an LEL of 1,000 ppm (368.3 mg/kg bw/day in males and 351.8 mg/kg bw/day in females). The LEL was based on decreases in mean body weights, body weight gains, and food consumption, and an increase in liver *N*-demethylase activity.

3. A 1-year dog feeding study with a NOEL of 1 mg/kg bw/day (40 ppm) and an LEL of 5 mg/kg bw/day (200 ppm), based on lenticular and corneal opacity and hepatic toxicity in either sex (the current Reference Dose was determined based on this study). A subsequent 1-year dog feeding study, using lower doses to further define the NOEL for tebuconazole, defines a systemic LOEL of 150 ppm (based on adrenal effects in both sexes) and a systemic NOEL of 100 ppm.

4. A 2-year rat chronic feeding study defined, a NOEL of 7.4 mg/kg bw/day (100 ppm) and a LEL of 22.8 mg/kg bw/day (300 ppm) based on body weight

depression, decreased hemoglobin, hematocrit, MCV and MCHC, and increased liver microsomal enzymes in females. Tebuconazole was not oncogenic at the dose levels tested (0, 100, 300, and 1,000 ppm).

5. A rat oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day based on elevation of absolute and relative liver weights. For developmental toxicity, a NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day was determined, based on delayed ossification of thoracic, cervical, and sacral vertebrae, sternum, fore and hind limbs and increase in supernumerary ribs.

6. A rabbit oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day based on depression of body weight gains and food consumption. A developmental NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day were based on increased postimplantation losses, from both early and late resorptions and frank malformations in eight fetuses of five litters.

7. A mouse oral developmental toxicity study with a maternal NOEL of 10 mg/kg bw/day and an LEL of 20 mg/kg bw/day based on a supplementary study indicating reduction in hematocrit and histological changes in liver. A developmental NOEL of 10 mg/kg bw/day and an LEL of 30 mg/kg bw/day based on dose-dependent increases in runts/dam at 30 and 100 mg/kg bw/day.

8. A mouse dermal developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and a LEL of 60 mg/kg bw/day based on a supplementary study indicating increased liver microsomal enzymes and histological changes in liver. The NOEL for developmental toxicity in the dermal study in the mouse is 1,000 mg/kg bw/day, the highest dose tested (HDT).

9. A two-generation rat reproduction study with a dietary maternal NOEL of 15 mg/kg bw/day (300 ppm) and a LEL of 50 mg/kg bw/day (1,000 ppm) based on depressed body weights, increased spleen hemosiderosis, and decreased liver and kidney weights. A reproductive NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/day (1,000 ppm) were based on neonatal birth weight depression.

10. An Ames mutagenesis study in *Salmonella* that showed no mutagenicity with or without metabolic activation.

11. A micronucleus mutagenesis assay study in mice that showed no genotoxicity.

12. A sister chromatid exchange mutagenesis study using CHO cells that was negative at dose levels 4 to 30  $\mu$ g/mL without activation or 15 to 120  $\mu$ g/mL with activation.

13. An unscheduled DNA synthesis (UDS) study that was negative for UDS in rat hepatocytes.

Additionally, a mouse oncogenicity study at dietary levels of 0, 20, 60, and 80 ppm for 21 months did not reveal any oncogenic effect for tebuconazole at any dose tested. Because the Maximum Tolerated Dose (MTD) was not reached in this study, the study was classified as supplementary. A followup mouse study at higher doses (0, 500, 1,500 ppm in the diet), with an MTD at 500 ppm, revealed statistically significant incidences of hepatocellular adenomas and carcinomas in males and carcinomas in females. The initial and followup studies, together with supplementary data submitted by Miles, Inc., were classified as core minimum.

The Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (CPRC) has classified tebuconazole as a Group C carcinogen (possible human carcinogen). This classification is based on the Agency's "Guidelines for Carcinogen Risk Assessment" published in the **Federal Register** of September 24, 1986 (51 FR 33992). The Agency has chosen to use the reference dose calculations to estimate human dietary risk from tebuconazole residues. The decision supporting classification of tebuconazole as a possible carcinogen (Group C) rather than a probable carcinogen (Group B) was primarily based on the statistically significant increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of NMRI mice both by positive trend and pairwise comparison at the HDT, and the structural correlation with at least six other related triazole pesticides that produce liver tumors.

The Reference Dose (RfD) is established at 0.01 mg/kg of body weight (bw)/day, based on a no-observed-effect level (NOEL) of 1.00 mg/kg bw/day and an uncertainty factor of 100. The NOEL is based on a 1-year dog feeding study that demonstrated lenticular and corneal opacity and hepatic toxicity as an endpoint effect. A chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. The Theoretical Maximum Residue Contribution

(TMRC) from the current action is estimated at 0.000078 mg/kg bw/day and utilizes 0.78% of the RfD for the general population of the 48 States. The TMRC for the most highly exposed subgroup, nonnursing infants (less than 1 year old), is estimated at 0.000097 mg/kg/day and utilizes less than 1% of the RfD.

The nature of the residue in barley, oats, and wheat is adequately understood. An adequate analytical method using high-performance liquid chromatography is available for enforcement purposes.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232.

Tolerances for tebuconazole in or on animal commodities are not currently required.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the

requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number, [PP 9F3818/R2153] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Written objections and hearing requests, identified by the document control number, [PP 9F3818/R2153], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests can be sent directly to EPA at:

opp-docket@epamail.epa.gov.

A copy of electronic objections and hearing requests may be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory

action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 28, 1995.

**Stephen L. Johnson,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 is amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 346a and 371.

2. In § 180.474, by revising the table therein, to read as follows:

#### § 180.474 Tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol); tolerances for residues.

\* \* \* \* \*

Commodity	Parts per million
Bananas .....	0.05
Barley, forage .....	0.10
Barley, grain .....	0.05
Barley, hay .....	0.10
Barley, straw .....	0.10
Oat, forage .....	0.10
Oat, grain .....	0.05
Oat, hay .....	0.10
Oat, straw .....	0.10
Peanuts .....	0.1
Peanut, hulls .....	4.0
Wheat, forage .....	0.10
Wheat, grain .....	0.05
Wheat, hay .....	0.10
Wheat, straw .....	0.10

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#### 40 CFR Part 180

[PP 0F3876/R2155; FRL-4967-8]

RIN 2070-AB78

#### Myclobutanil; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This rule establishes tolerances for the combined residues of the fungicide myclobutanil and a metabolite in or on the raw agricultural commodities almond nutmeat at 0.1 part per million (ppm) and almond hulls at 2.0 ppm, and increases the tolerances established for milk to 0.2 ppm and meat to 0.1 ppm, meat byproducts (except liver) to 0.2 ppm and liver to 1.0 ppm for cattle, goats, hogs, horses, and sheep. Rohm & Haas Co. requested in a petition submitted pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) the regulation to establish a maximum permissible level for residues of myclobutanil on almond nuts and almond hulls. EPA initiated the increased tolerances for milk, meat, meat byproducts, and liver based on the additional residues in or on almond nuts and almond hulls.

**EFFECTIVE DATE:** This regulation became effective on July 27, 1995.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 0F3876/R2155], may be submitted to: Hearing